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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,851	08/18/2003	Anne M. Pianca	AB-334U	4016
23845	7590	12/01/2005	EXAMINER	
ADVANCED BIONICS CORPORATION 25129 RYE CANYON ROAD VALENCIA, CA 91355			ALTER, ALYSSA M	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,851

Applicant(s)

PIANCA ET AL.

Examiner

Alyssa M. Alter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 8, filed September 5, 2005, with respect to the rejection(s) of claim(s) 1-20 under 35 U.S.C. 112 2nd paragraph, 35 U.S.C. 102(e) and 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Lord et al. (US 5,390,671).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 6, 8-14 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Lord et al. (US 5,390,671). Lord et al. discloses an insertion set for a transcutaneous placement of a sensor within the patient's body. The insertion set comprises a slotted insertion needle, which extends through the mounting base adapted for mounting to the patient's skin. The examiner considers the slotted insertion needle to be the cannula having a slit, the sensor to be the elongated medical device and the mounting base to be the reference platform.

"The proximal and distal segments of the sensor are linearly offset or misaligned so that the distal segment can be fitted into the slotted insertion needle for

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transcutaneous placement as the mounting base is pressed onto the patient's skin. The insertion needle can be withdrawn from the mounting base, leaving the sensor distal segment at the selected position within the patient, such as a subcutaneous, intravascular, intramuscular, or intravenous site" (col. 1-2, lines 64-68 and 1-4, respectively).

As seen in figures 2 and 4, the sensor comprises an offset portion, transition segment 26, which extends from the needle. The examiner considers the offset portion to form a lead lock, since a portion of the medical device is secured within the needle or cannula lumen.

Furthermore, the sensor 12 distal segment comprises several sensor electrodes 18. Therefore, since the sensor is flat with several electrodes, the examiner considers it to be a paddle electrode. In the "withdrawal step, as illustrated in FIG. 7, the insertion needle 14 slides over the sensor distal segment 16, leaving the sensor electrodes 18 at the selected insertion site" (col. 4, lines 57-60).

As to claim 11, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Therefore, since the sensor electrodes 18, or paddle electrode is connected to the monitor 32, it is inherently capable of being in electrical connection with an external trial stimulator.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 2-5, 7 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lord et al. (US 5,390,671) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lord et al. (US 5,390,671) in view of Lobdill et al. (US 6,413,263).

According to Merriam-Webster {see Reference U}, stereotactic or stereotaxic means "of, relating to, or being a technique or apparatus used in neurological research or surgery for directing the tip of a delicate instrument (as a needle or an electrode) in three planes in attempting to reach a specific locus in the brain." Therefore, the examiner considers the insertion set to comprise a stereotactic frame since the insertion set can direct a delicate instrument to a specific locus.

In the alternative, although the examiner considers Lord et al. to disclose a stereotactic frame above, Lobdill et al. further teaches that it is known to use stereotactic frame and stereotactic placement, in order to providing stability and maintenance of proper probe placement. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the insertion set as taught by Lord et al. with the stereotactic frame as taught by Lobdill et al., in order to maintain stability and accuracy with the placement of the slotted insertion needle and the medical device.

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2. Claims 17-20 are rejected under 35 U.S.C. 103(a) as obvious over Lord et al. (US 5,390,671). Lord et al. discloses the claimed invention but does not disclose expressly securing the lock to the lead through clamping, pinching, suturing or piercing means. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify securing the lock to the lead as taught by Lord et al., with the clamping, pinching, suturing or piercing means, because Applicant has not disclosed the other securing means provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with securing the lock to the lead as taught by Lord et al., because both means lock the lead in position to prevent unwanted movement of the lead.

Therefore, it would have been an obvious matter of design choice to modify the securing means of the lock to the lead to obtain the invention as specified in the claim(s).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Gielen et al. (US 6,011,996) discloses a stereotactic frame for brain target localization.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GEORGE R. EVANISKO
PRIMARY EXAMINER

11/29/5

Alyssa M. Alter

Alyssa M Alter
Examiner
Art Unit 3762

AA